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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/656,918
Filing Date: September 05, 2003
Appellant(s): FORBES JONES ET AL.

Mark R. Leslie
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 2 July 2009 appealing from the Office action mailed 18 August 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

US 3,356,542	Smith	12-1967
US 4,820,485	Ototani et al.	04-1989
US 6,342,068	Thompson	01-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-2, 4-8, 10, 12, 16-20, 32-34 and 53-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (US 3,356,542).

In regards to claims 1-2, 4, 6, 8, 10 and 12, Smith ('542) discloses an alloy having favorable fatigue resistance (col. 1, line 62 – col. 2, line 14). A comparison of the alloy disclosed by Smith ('542) in comparison with that of the instant invention is shown in the table below (col. 4, line 23 –col. 5, line 11).

Element	**From Instant Claims** (weight percent)	**Smith ('542)** (weight percent)	**Overlap** (weight percent)
Claim 1			
Co	at least 20	at least 25	at least 25
Ni	32.7 – 37.3	5 – 45	32.7 – 37.3
Cr	18.75 – 21.25	13 – 25	18.75 – 21.25
Mo	8.85 – 10.65	7 – 16	8.85 – 10.65
N	less than 30 ppm	0 – 0.05	less than 30 ppm
Ti	less than 0.7	0 – 2.0	less than 0.7
Al	at least 0.05	0—2.0	0.05 – 2.0
Fe	less than 1.05	0 – 6.0	less than 1.05

Claim 2			
N	less than 20 ppm	0 – 0.05	less than 20 ppm
Claim 4			
Ti	less than 0.03	0 – 2.0	less than 0.03
Claim 6			
Ni	33 – 37	5 – 45	33 – 37
Cr	19 – 21	13 – 25	19 – 21
Mo	9 – 10.5	7 – 16	9 – 10.5
Claim 8			
N	less than 20 ppm	0 – 0.05	less than 20 ppm
Claim 10			
Ti	less than 0.03	0 – 2.0	less than 0.03
Claim 12			
Al	0.05 – 0.15	0 – 2.0	0.05 – 0.15

The ranges disclosed by Smith (‘542) for cobalt, nickel, chromium, molybdenum, nitrogen, titanium, aluminum, and iron are within the ranges claimed of the instant invention. The Examiner notes that the disclosed composition of the alloy overlaps the the composition of the claimed invention. Therefore, a prima facie case of obviousness exists. See MPEP 2144.05 I. It would have been obvious to one of ordinary skill in the art at the time the invention was made to select the claimed compositions of an alloy from the compositions disclosed by Smith (‘542) because Smith (‘542) discloses the same utility (alloy wire) throughout the disclosed ranges.

Still regarding claim 1, Smith (‘542) does not specify wherein the alloy would include spherical oxide inclusions and would be substantially free of titanium nitride and mixed metal carbonitride inclusions. However, the composition of titanium, nitrogen, and carbon within the alloy can be non-existent as specified by Smith (‘542) (col. 4, line 69 – col. 5, line 11). Further, Smith (‘542) discloses arc melting and induction melting in a vacuum atmosphere as methods of preparing the alloy, which would be substantially the same techniques of producing the alloys of the instant invention (col. 4, lines 23-42 and

col. 5, lines 11-30). Therefore, in absence of evidence to the contrary, it would be expected that the alloys of Smith (‘542) would have generally spherical oxide inclusions and be substantially free of titanium nitride and mixed metal carbonitride inclusions. See MPEP 2112.01 I.

With respect to the recitation “at least one of at least 0.05 to 0.15 weight percent aluminum, at least 5 to 20 ppm calcium, at least 5 to 50 ppm magnesium, and at least 5 to 50 ppm cerium;" and "no greater than 0.035 weight percent carbon", Smith (‘542) discloses adding 0 to 2 weight percent aluminum in the (col. 5, lines 3-10) and no more than 0.05 weight percent of carbon, boron, oxygen, nitrogen, or beryllium to the cobalt-based alloy (col. 4, line 23 – col. 5, line 11) that would form a wire or cable (col. 3, lines 64-75).

In regards to claim 5, the Examiner notes that neither the instant invention nor the alloy disclosed by Smith (‘542) necessitate the presence of manganese, phosphorus, silicon or sulfur. Smith (‘542) discloses that the carbon content and boron content would be maintained to less than 0.05 weight percent (col. 4, line 68 – col. 5, line 2).

In regards to claim 7, the Examiner notes that neither the instant invention nor the alloy disclosed by Smith (‘542) necessitate the presence of manganese, phosphorus, silicon, or sulfur. Smith (‘542) discloses that the carbon content and boron content would be maintained to less than 0.05 weight percent and the content of iron would be less than 6 weight percent (col. 4, line 23 – col. 5, line 2).

In regards to claim 16, Smith (‘542) discloses an alloy having favorable fatigue

resistance and teaches adding no more of 2 weight percent each and no more than 4 weight percent total of aluminum, titanium, and zirconium to prevent embrittlement and grain boundary second phase formation and the oxygen content would be no more than 0.05 weight percent (which includes 0 weight percent) (col. 4, line 69 – col. 5, line 11). Smith ('542) further discloses the same alloy composition formed by a substantially similar process. Therefore, the material properties of the alloy would be expected to be similar. See MPEP 2112.01 I.

In regards to claim 17, Smith ('542) discloses an alloy having favorable fatigue resistance and teaches adding no more than 2 weight percent each and no more than 4 weight percent total of aluminum, titanium, and zirconium (which includes 0 weight percent) (col. 4, line 69 – col. 5, line 11). Therefore, the alloy would not necessarily be comprised of titanium or the alloy may contain a very small content of titanium and hence be substantially free of titanium.

In regards to claim 18, Smith ('542) discloses an alloy having favorable fatigue resistance and teaches adding no more than 0.05 weight percent each and no more than 0.10 weight percent (which includes 0 weight percent) of carbon, boron, oxygen, nitrogen or beryllium. Therefore, the alloy would not necessarily be comprised of nitrogen or the alloy may contain a very small content of nitrogen and hence be substantially free of nitrogen.

In regards to claim 19, Smith ('542) discloses an alloy having favorable fatigue resistance and teaches yield strengths of at least 200,000 psi (200 ksi) (col. 5, lines 46-63). Furthermore, Smith ('542) discloses the same composition made by a substantially

similar process. Therefore, the properties of the product would inherently be similar. See MPEP 2112.01 I.

In regards to claim 20, Smith ('542) discloses an alloy having favorable fatigue resistance and teaches an alloy composition having the same composition as the instant invention and a process of making the alloy (vacuum induction melting and vacuum arc melting) that is substantially similar to that of the instant invention. Therefore, it would be expected that alloy would qualify for use in surgical implant applications under ASTM standard specification F 562.

In regards to claims 32-34, Smith ('542) discloses an alloy having favorable fatigue resistance and teaches making the alloy into articles of manufacture including wire and cable (col. 3, lines 64-75). The wire would be made of the same composition as the instant invention and the process of making the alloy (vacuum induction melting and vacuum arc melting) is substantially similar to that of the instant invention. Therefore, it would be expected that the alloy would qualify for use in surgical implant applications under ASTM standard specification F 562.

In regards to claim 53-54, Smith ('542) discloses an alloy wire having favorable fatigue resistance (col. 1, line 62 – col. 2, line 14 and col. 3, lines 64-75). A comparison of the alloy disclosed by Smith ('542) in comparison with that of the instant invention is shown in the table on the following page (col. 4, line 23 –col. 5, line 11).

Element	**From Instant Claims** (weight percent)	**Smith ('542)** (weight percent)	**Overlap** (weight percent)
Claim 53			
Co	at least 20	at least 25	at least 25
Ni	32.7 – 37.3	5 – 45	32.7 – 37.3
Cr	18.75 – 21.25	13 – 25	18.75 – 21.25
Mo	8.85 – 10.65	7 – 16	8.85 – 10.65
N	less than 30 ppm	0 – 0.05	less than 30 ppm
Ti	less than 0.7	0 – 2.0	less than 0.7
Al	at least 0.05 – 0.15	0 – 2.0	0.05 – 2.0
Fe	less than 1.05	0 – 6.0	less than 1.05

Still regarding claim 53, the Examiner notes that the instant invention would not necessitate the addition of manganese, phosphorus, or silicon because "no greater than" includes 0 weight percent. Smith ('542) discloses adding no more than 0.05 weight percent of carbon, boron, oxygen, nitrogen, or beryllium to the cobalt-based alloy (col. 4, line 23 – col. 5, line 11).

The ranges disclosed by Smith ('542) for cobalt, nickel, chromium, molybdenum, nitrogen, titanium, aluminum, and iron are within the ranges claimed of the instant invention. The Examiner notes that the disclosed composition of the alloy overlaps with the composition of the claimed invention. Therefore, a prima facie case of obviousness exists. See MPEP 2144.05 I. It would have been obvious to one of ordinary skill in the art at the time the invention was made to select the claimed compositions of an alloy from the compositions disclosed by Smith ('542) because Smith ('542) discloses the same utility (alloy wire) throughout the disclosed ranges (col. 3, lines 64-75).

Still regarding claim 53, Smith ('542) does not specify wherein the alloy would include spherical oxide inclusions and be substantially free of titanium nitride and mixed metal carbonitride inclusions. However, the composition of titanium, nitrogen, and

carbon within the alloy can be non-existent as specified by Smith (‘542) (col. 4, line 69 – col. 5, line 11). . Further, Smith (‘542) discloses arc melting and induction melting in a vacuum atmosphere as methods of preparing the alloy, which would be substantially the same techniques of producing the alloys of the instant invention (col. 4, lines 23-42 and col. 5, lines 11-30). Therefore, in absence of evidence to the contrary, it would be expected that the alloys of Smith (‘542) would have generally spherical oxide inclusions and be substantially free of titanium nitride and mixed metal carbonitride inclusions. See MPEP 2112.01 I.

Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (US 3,356,542) as applied to claim 1, and further in view of Ototani et al. (US 4,820,485).

In regards to claims 13-15, Smith (‘542) discloses a cobalt-based alloy, but Smith (‘542) does not specify wherein the alloy would contain 5 to 20 ppm calcium (claim 13), 5 to 50 ppm calcium (claim 14), or 5 to 50 ppm cerium.

Ototani et al. (‘485) disclose adding 5 to 100 ppm calcium and 0 to 200 ppm rare earth element (cerium) to a cobalt-, nickel-, or iron-based alloy in order to perform deoxidation, desulfurization, and denitrification of the alloy (col. 7, line 65 – col. 8, line 60 and col. 10, lines 45-57).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add 5 to 100 ppm calcium and 0 to 200 ppm rare earth element (cerium), as disclosed by Ototani et al. (‘485), to the cobalt-based alloy as disclosed by Smith ('542), in order to perform deoxidation, desulfurization, and

denitrification of the alloy, as disclosed by Ototani et al. (’485) (col. 7, line 65 – col. 8, line 60 and col. 10, lines 45-57).

Claims 20, 32-34 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (US 3,356,542) as applied to claim 1, and further in view of Thompson (US 6,342,068).

In regards to claims 20, 32-34 and 54, Smith (‘542) discloses a cobalt-based alloy that would be used as a wire or cable (col. 3, lines 64-75), but Smith ('542) does not specify that the cobalt-based alloy would be used as a stent (surgical implant device).

Thompson (‘068) discloses that cobalt-based alloys would be used as stents because of their biocompatibility, fatigue resistance, and corrosion resistance (col. 6, lines 21-34).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the cobalt-based alloy, as disclosed by Smith ('542), as a stent, as disclosed by Thompson ('068), because cobalt-based alloys would have biocompatibility, fatigue resistance, and corrosion resistance, as disclosed by Thompson ('068) (col. 6, lines 21-34).

Still regarding claim 34, the Examiner asserts that the alloy disclosed by Smith (‘542) would meet the ASTM standard specification F 562, because Smith (‘542) discloses substantially the same alloy composition as that of the instant invention.

(10) Response to Argument

The Appellant's arguments have been fully considered but are not persuasive.

First, the Appellant primarily argues that the discovery of a modified MP35N-type alloy that includes less than 30 ppm nitrogen, less than 0.7 weight percent titanium and minor amounts of at least one of aluminum, calcium, magnesium, and cerium was made by the Appellant and has a microstructure that is substantially free of the problematic titanium nitride and mixed metal carbonitride inclusions the Appellant has identified. The Appellant further argues that the substantial change in microstructure was unexpected and significant since spherical oxide inclusions were formed in the modified MP35N-type alloy and did not significantly score wire drawing dies, reducing the incidence of surface defects on wire drawn through the dies, and also did not produce regions of substantially increased stress within the drawn wire and this was not merely a slight adjustment to the microstructure of the conventional MP35N alloy, but instead was a significant technical breakthrough that produced a fundamentally different alloyed microstructure that addressed microstructural drawbacks that the inventors discovered were present in the conventional MP35N alloy.

In response, Smith ('542) discloses an alloy having favorable fatigue resistance (col. 1, line 62 – col. 2, line 14). A comparison of the alloy disclosed by Smith ('542) in comparison with that of the instant invention is shown in the on the following page (col. 4, line 23 – col. 5, line 11).

Element	From Instant Claims (weight percent)	Smith ('542) (weight percent)	Overlap (weight percent)
Claim 1			
Co	at least 20	at least 25	at least 25
Ni	32.7 – 37.3	5 – 45	32.7 – 37.3
Cr	18.75 – 21.25	13 – 25	18.75 – 21.25
Mo	8.85 – 10.65	7 – 16	8.85 – 10.65
N	less than 30 ppm	0 – 0.05	less than 30 ppm
Ti	less than 0.7	0 – 2.0	less than 0.7
Al	at least 0.05	0—2.0	0.05 – 2.0
Fe	less than 1.05	0 – 6.0	less than 1.05

Additionally, Smith ('542) does not specify that the alloy would include spherical oxide inclusions and would be substantially free of titanium nitride and mixed metal carbonitride inclusions. However, the presence of titanium, nitrogen, and carbon within the alloy can be non-existent as specified by Smith ('542) (col. 4, line 69 – col. 5, line 11). Further, Smith ('542) discloses arc melting and induction melting in a vacuum atmosphere as methods of preparing the alloy, which would be substantially the same techniques of producing the alloys of the instant invention (col. 4, lines 23-42 and col. 5, lines 11-30). Therefore, it would be expected that the alloys of Smith ('542) would have generally spherical oxide inclusions and be substantially free of titanium nitride and mixed metal carbonitride inclusions. MPEP 2112.01 I.

Second, the Appellant primarily argues that as a result of the microstructural changes the present inventors produced small-diameter wire from the alloy recited in claim 1 was found to exhibit unexpected and substantially improved fatigue resistance relative to conventional MP35N alloy such as in Table 9 of the Present Application where at 100 ksi, a stress level similar to that which pacing leads are subjected *in vivo*, wire formed from the alloy of the present invention withstood at least 797% the number

of cycles in rotary beam fatigue testing than wire produced from conventional MP35N alloy.

In response, the Examiner notes (see Table 9) that the standard MP35N alloy has an improved fatigue resistance over modified MP35N alloy at a stress value of 250 ksi. At 250 ksi standard MP35N alloy withstood 116% (11,129/9,586) the number of cycles in rotary beam fatigue testing than wire produced from modified MP35N alloy. Therefore, the modified MP35N alloy would not patentably distinguish from the conventional MP35N alloy.

Third, the Appellant primarily argues that there is no motivation to take specific steps as reducing nitrogen content to less than 30 ppm and make modifications to alloy chemistry and processing which the inventors discovered avoids the problematic microstructure present in conventional MP35N alloy.

In response, the Examiner notes that independent claim 1 (line 7) recites “less than 30 ppm nitrogen”. Although Smith (‘542) teaches 0 to 0.05 weight percent nitrogen, the Appellant’s burden is to establish the criticality of the range of less than 30 ppm nitrogen over the range of 0 to 0.05 weight percent nitrogen (i.e. the difference between 30 ppm nitrogen and less than 30 ppm nitrogen), which has not been met by the Appellant. MPEP 716.02(d)(II). Further, Smith (‘542) discloses arc melting and induction melting in a vacuum atmosphere as methods of preparing the alloy, which would be substantially the same techniques of producing the alloys of the instant invention (col. 4, lines 23-42 and col. 5, lines 11-30).

The rejection of claim 1 under 35 U.S.C. 103(a) as being unpatentable over Smith ('542).

Fourth, the Appellant primarily argues that the Examiner has not established a *prima facie* case of obviousness based on Smith ('542) because Smith ('542) neither teaches nor suggests all of the elements and limitation of claim 1, specifically the limitation "less than 30 ppm nitrogen" in line 7 of claim 1 since Smith ('542) only briefly refers to nitrogen in the passage at column 4, lines 68-72:

> It is critically important that the alloy composition contain no more than 0.05% of carbon, boron, oxygen, nitrogen, or beryllium, the total of these components being no more than 0.1%.

The Appellant further argues that this disclosure in Smith ('542) merely describes an upper limit for nitrogen in the alloy; that limit is 0.05%, which is 500 ppm, a value more than 16 times greater than the critical value of less than 30 ppm discovered by the Appellant; Smith ('542) does not in any way focus on nitrogen as being particularly important relative to other listed elements; and the Examiner reads the above-quoted sentence of Smith ('542) as referring to a nitrogen range of 0 up to 500 ppm, which is an incorrect interpretation.

In response, the Examiner notes that Smith ('542) discloses that the lower limit of nitrogen would necessarily be 0 weight percent and the upper limit would necessarily be 0.05 weight percent (column 4, lines 68-72). The Appellant's burden is to establish the c criticality of the range of less than 30 ppm nitrogen over the range of 0 to 0.05 weight percent nitrogen (i.e. the difference between 30 ppm nitrogen and less than 30 ppm nitrogen), which has not been met by the Appellant. MPEP 716.02(d)(II).

Fifth, the Appellant primarily argues that even if it can be said that the statement

in Smith ('542) that the alloy contains "no more than 0.05%" (500 ppm) of nitrogen includes the complete absence (0%) of nitrogen, that statement is not sufficiently specific to teach or suggest the limitation "less than 30 ppm nitrogen", a limitation which Appellant has discovered is critical to the performance of the claimed alloy. The Appellant further argues that the decision cited in MPEP §2131.03 is particularly *Atofina* pertinent here because in *Atofina*, the U.S. Court of Appeals for the Federal Circuit considered whether a prior art reference's teaching of a temperature range of 100 to 500°C effectively disclosed the 330 to 450°C temperature recited in a claim and held it did not, even though the claimed range was fully encompassed by the prior art range.

> Here, the prior art, JP 51-82250, discloses a temperature range of 100 to 500°C which is broader than and fully encompasses the specific temperature range claimed in the '514 patent of 330 to 450°C. Given the considerable difference between the claimed range and the range in the prior art, no reasonable fact finder could conclude that the prior art describes the claimed range with sufficient specificity to anticipate this limitation of the claim. Because the court's determination that JP 51-82250 disclosed the temperature range in claims 1, 2, 6, 7, 9, and 10 of the '514 patent was [erroneous], we must reverse its finding of anticipation based on the temperature range.

The Appellant further argues that *Atofina* went even further – in discussing a second prior art reference that referred to a temperature range of 150 to 350°C, the court held:

> [T]he disclosure of a range of 150 to 350°C does not constitute a specific disclosure of the endpoints of that range, *i.e.*, 150°C and 350°C, as Great Lakes asserts. The disclosure is only that of a range, not a specific temperature in that range, and the disclosure of a range is no more a disclosure of the end points of the range than it is of the intermediate points.

Thus, a prior art reference disclosing a broad range must expressly or implicitly refer to a sub-range with a relatively high degree of specificity to support the rejection of a claim

reciting the sub-range. Echoing the Federal Circuit's interpretation in *Atofina*, MPEP §2131.02 explains that the question of what constitutes "sufficient specificity" is similar to that of whether a generic teaching "clearly envisages" a species which is discussed in MPEP §2131.02 as follows:

> If one of ordinary skill in the art is able to 'at once envisage' the specific compound within the generic chemical formula, the compound is anticipated. One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be 'at once envisaged.' ...

In response, the Examiner first notes that MPEP §2131.03 deals with anticipation (i.e. 35 U.S.C. 102), whereas the claims are rejected based on obviousness (i.e. 35 U.S.C. 103). Although the range of up to 0.05 weight percent nitrogen (equivalent to 500 ppm nitrogen), as disclosed by Smith ('542) at column 4, lines 68-72, is broader than the "less than 30 ppm nitrogen", the Appellant has failed to show that this range would provide unexpected results over the prior art range of 0 to 500 ppm nitrogen. To establish unexpected results over a claimed range, the Appellant should compare a sufficient number of tests both inside and outside the claimed range to show the criticality of the claimed range. MPEP 716.02(d)(II). Additionally, the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. MPEP 2144.05 II.

Sixth, the Appellant primarily argues that the Lippard Declaration addresses what one having ordinary skill would have been taught by Smith ('542) regarding nitrogen content in the alloy of Smith ('542). The Lippard Declaration confirms that at the time the

Present Application was filed one having ordinary skill would not have read Smith ('542) to teach or suggest limiting nitrogen in the Smith (‘542) alloy to less than 30 ppm. The Lippard Declaration includes these statements:

> 12. I have thoroughly reviewed U.S. Patent No. 3,356,542 issued to Smith ("Smith"). Smith does not describe or suggest an alloy that includes less than 30 ppm of nitrogen. Although Smith does state that the alloy described in that patent should include "no more than 0.05%" nitrogen, that level is more than 15 times the maximum nitrogen level critical to the invention described in the Application. Smith does not describe or suggest that there is any benefit whatsoever to limiting the nitrogen level in the alloy of that patent to less than 30 ppm, or even to very small, ppm range, concentrations.
>
> 13. Given that Smith does not state or suggest that that the alloy in that patent has or would benefit from having less than 30 ppm nitrogen, or even very low (ppm range) nitrogen levels, the alloy of Smith would certainly have included at least 50 ppm nitrogen. For example, 50 ppm is the minimum level of nitrogen found in conventional MP35N alloy. Although Smith does refer offhand to vacuum melting, such techniques were well known at the time, and Smith does not state or suggest that melting under vacuum should be done for reducing alloy nitrogen levels or otherwise. Smith does not state or suggest any reason why one would have undertaken the involved, time-consuming, and costly steps necessary to limit nitrogen in the alloy described in Smith to less than 30 ppm or to any other extremely low level.
>
> 14. Absent limiting nitrogen to these very low levels recited in claim 1, alloy microstructure could not be substantially free of titanium nitride and mixed metal carbonitride inclusions. Also, Smith does not specifically describe or otherwise suggest a microstructure that is substantially free of titanium nitride and mixed metal carbonitride inclusions. Accordingly, Smith does not teach or suggest an alloy having a microstructure that is substantially free of titanium nitride and mixed metal carbonitride inclusions and, instead, includes well-tolerated substantially spherical oxide inclusions, as is recited in claim 1.

In response to the first two passages, the Examiner notes that although Smith ('542) does not demonstrate the benefit to limiting the nitrogen level in the alloy to less

than 30 ppm, the Appellant has failed to show that this range would provide unexpected results over the prior art range of 0 to 500 ppm nitrogen. To establish unexpected results over a claimed range, the Appellant should compare a sufficient number of tests both inside and outside the claimed range (i.e. 30 ppm nitrogen versus less than 30 ppm nitrogen) to show the criticality of the claimed range. MPEP 716.02(d)(II). Additionally, one having ordinary skill in the art knows that formation of an alloy under vacuum conditions is done to limit the presence of gaseous impurities (such as nitrogen) in the alloy that have been found to be detrimental to the alloy structure as in alloys formed in air. In response to the third passage, the Examiner notes that claim 1 recites "less than 0.7 weight percent titanium". Smith ('542) discloses adding 0 to 2 weight percent each of aluminum, titanium, and zirconium with a total of no more than 4 weight percent (col. 5, lines 3-10) and no more than 0.05 weight percent of carbon, boron, oxygen, nitrogen, or beryllium (col. 4, lines 68-72). Thus, even with nitrogen present in the alloy of Smith ('542), the alloy could still be substantially free of titanium nitride and carbonitride inclusion if titanium and carbon are absent in the alloy of Smith ('542) since Smith ('542) does not require the presence of carbon and titanium.

Seventh, the Appellant primarily argues that in the Final Office Action (Office Action of 18 August 2008), the Examiner only refers to the Lippard Declaration as being from an inventor named in the Present Application, but does not address the declaratory evidence presented in the declaration regarding the teaching of Smith ('542). Additionally, the Appellant argues that the Examiner is required to carefully weigh the uncontroverted statements regarding Smith ('542) in the Lippard Declaration. MPEP

§2145 states that "[c]onsideration of rebuttal evidence and arguments requires Office personnel to weigh the proffered evidence and arguments" and that "Office personnel should avoid giving evidence no weight, except in rare circumstances". The Appellant further argues that there is no basis in the record to ignore or devalue the statements in the Lippard Declaration and those statement should be accepted at face value. MPEP 716.02(g).

In response, the Examiner notes that establishing long-felt need requires objective evidence that an art recognized problem existed in the art for a long period of time without solution. The relevance of long-felt need and the failure of others to the issue of obviousness depends on several factors. First, the need must have been a persistent one that was recognized by those of ordinary skill in the art. Second, the long-felt need must not have been satisfied by another before the invention by the Appellant. Third, the invention must in fact satisfy the long-felt need. MPEP 716.04. The Appellant has failed to provide evidence that a lack of fatigue resistance was recognized by others (i.e. not the Appellant) for a long period of time without a solution nor has the Appellant provided evidence of any prior unsuccessful attempts to improve fatigue resistance.

Eighth, the Appellant primarily argues that there existed no clear understanding in the deficiencies in the conventional alloy's microstructure when formed into wire used in cardiac pacemaker lead wires and in other surgical implant applications. Because the problems inherent in conventional MP35N alloy were not known before being discovered by the Appellant, there would have existed no motivation or suggestion to

modify the microstructure of the Smith ('542) alloy so that it substantially lacked titanium nitride and mixed carbonitride inclusions and, instead, includes generally spherical oxide inclusions, as in claim 1. The Appellant further argues that there would have existed no motivation to take the specific steps, such as reducing nitrogen content to less than 30 ppm and making other modifications to alloy chemistry and processing, which the inventors discovered avoids the problematic microstructure present in conventional MP35N alloy, which were both unexpected and significant.

In response, the Examiner notes that there could have been not have been a persistent need of such an alloy if the problems associated with the MP35N alloy were not known before being discovered by the Appellant. Additionally, the Examiner notes that Smith (‘542) discloses an alloy having favorable fatigue resistance (col. 1, line 62 – col. 2, line 14). A comparison of the alloy disclosed by Smith (‘542) in comparison with that of the instant invention is shown in the on the following page (col. 4, line 23 – col. 5, line 11).

Element	**From Instant Claims** (weight percent)	**Smith (‘542)** (weight percent)	**Overlap** (weight percent)
Claim 1			
Co	at least 20	at least 25	at least 25
Ni	32.7 – 37.3	5 – 45	32.7 – 37.3
Cr	18.75 – 21.25	13 – 25	18.75 – 21.25
Mo	8.85 – 10.65	7 – 16	8.85 – 10.65
N	less than 30 ppm	0 – 0.05	less than 30 ppm
Ti	less than 0.7	0 – 2.0	less than 0.7
Al	at least 0.05	0—2.0	0.05 – 2.0
Fe	less than 1.05	0 – 6.0	less than 1.05

Smith (‘542) does not specify that the alloy would include spherical oxide inclusions and would be substantially free of titanium nitride and mixed metal

carbonitride inclusions. However, the presence of titanium, nitrogen, and carbon within the alloy can be non-existent as specified by Smith ('542) (col. 4, line 69 – col. 5, line 11). Further, Smith ('542) discloses arc melting and induction melting in a vacuum atmosphere as methods of preparing the alloy, which would be substantially the same techniques of producing the alloys of the instant invention (col. 4, lines 23-42 and col. 5, lines 11-30). Therefore, it would be expected that the alloys of Smith ('542) would have generally spherical oxide inclusions and be substantially free of titanium nitride and mixed metal carbonitride inclusions and specific steps outside the disclosure of Smith ('542) would not be required. MPEP 2112.01 I.

Ninth, the Appellant primarily argues that the Examiner reaching a sweeping and unsupported conclusion that the broad alloy composition of Smith ('542) discloses would have rendered obvious the much narrower composition recited in claim 1 is impermissible hindsight and should be reversed.

In response to Appellant's argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Appellant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

The rejection of claims 2, 4-8, 10, 12, 16-20, 32-34 and 53-54 under 35 U.S.C. 103(a) as being unpatentable over Smith ('542).

Tenth, the Appellant primarily argues that because the Examiner did not meet the burden in establishing a *prima facie* case in claim 1 that the rejection of claims 2, 4-8, 10, 12, 16-20, 32-34 and 53-54 under 35 U.S.C. 103(a) as being unpatentable over Smith (‘542) should be reversed.

In response, the Examiner notes that a Smith (‘542) discloses an overlapping composition in addition to substantially similar processing. Therefore, the Examiner asserts that a *prima facie* case of obviousness has been established. MPEP 2144.05 I and MPEP 2112.01 I.

The rejection of claims 13-15 under 35 U.S.C. 103(a) as being unpatentable over Smith (‘542) as applied to claim 1, and further in view of Ototani (‘485).

Eleventh, the Appellant primarily argues that because the Examiner did not meet the burden in establishing a *prima facie* in claim 1 that the rejection of claims 13-15 under 35 U.S.C. 103(a) as being unpatentable over Smith ('542), and further in view of Ototani ('485) should be reversed.

In response, the Examiner notes that a Smith (‘542) discloses an overlapping composition in addition to substantially similar processing. Therefore, the Examiner asserts that a *prima facie* case of obviousness has been established. MPEP 2144.05 I and MPEP 2112.01 I.

The rejection of claims 20, 32-34 and 54 under 35 U.S.C. 103(a) as being unpatentable over Smith (‘542) as applied to claim 1, and further in view of Thompson (‘068).

Twelfth, the Appellant primarily argues that because the Examiner did not meet the burden in establishing a *prima facie* in claim 1 that the rejection of claims 20, 32-34 and 54 under 35 U.S.C. 103(a) as being unpatentable over Smith ('542), and further in view of Ototani ('485) should be reversed.

In response, the Examiner notes that a Smith (‘542) discloses an overlapping composition in addition to substantially similar processing. Therefore, the Examiner asserts that a *prima facie* case of obviousness has been established. MPEP 2144.05 I and MPEP 2112.01 I.

Secondary Considerations: Long-Felt and Unmet Need

Thirteenth, the Appellant primarily argues that even if the Examiner did establish a *prima facie* case of obviousness of any of the claims based on Smith ('542), Smith ('542) in view of Ototani (‘485), or Smith (‘542) in view of Thompson (‘068), Appellant’s claim 1 addresses a long-felt need that was unmet before the invention recited in claim 1 was made by the present inventors. In particular, a need existed for a new MP35N-type alloy having substantially improved fatigue resistance over conventional MP35N alloy and that could be formed into small-diameter alloy wire for use in cardiac pacemaker leads and other surgical implants and this need was not met until the present inventor conceived of the alloy recited in claim 1. The Appellant additionally argues that the Lippard Declaration shows that the need was recognized, persistent, and had not been solved by others and there exists no evidence or suggestion that the

failure of others to solve the long-felt need was not due to lack of interest or lack of appreciation of an invention potential or marketability and the evidence submitted to the Examiner rebuts any *prima facie* case of obviousness of the claims that the Examiner may have established.

In response, the Examiner notes that establishing long-felt need requires objective evidence that an art recognized problem existed in the art for a long period of time without solution. The relevance of long-felt need and the failure of others to the issue of obviousness depends on several factors. First, the need must have been a persistent one that was recognized by those of ordinary skill in the art. Second, the long-felt need must not have been satisfied by another before the invention by the Appellant. Third, the invention must in fact satisfy the long-felt need. MPEP 716.04. The Appellant has failed to provide evidence that a lack of fatigue resistance was recognized by others (i.e. not the Appellant) for a long period of time without a solution nor has the Appellant provided evidence of any prior unsuccessful attempts to improve fatigue resistance. Additionally, the Examiner notes (see Table 9) that the standard MP35N alloy has an improved fatigue resistance over modified MP35N alloy at a stress value of 250 ksi. At 250 ksi standard MP35N alloy withstood 116% (11,129/9,586) the number of cycles in rotary beam fatigue testing than wire produced from modified MP35N alloy. Since the pending claims do not recite a stress value or range of stress values applied to the alloy for which the fatigue resistance of the modified MP35N alloys are greater than the fatigue resistance of the conventional MP35N alloys there are stress values (i.e. 250 ksi) where standard MP35N alloy has better properties than

modified MP35N alloy, the modified MP35N alloy would not patentably distinguish from the conventional MP35N alloy. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Secondary Considerations: Surprising and Unexpected Results

Fourteenth, the Appellant primarily argues that the present Application includes evidence that the fatigue properties of wire formed from the alloy recited in claim 1 are substantially improved over wire formed from conventional MP35N alloy and during prosecution the Appellant submitted the Lippard Declaration providing detailed and uncontradicted evidence of unexpected results which the Examiner apparently discounts for reasons that cannot be determined clearly from the record and cannot be sustained. The Appellant further argues that Smith ('542) does not teach a range of 0 to 500 ppm nitrogen to one having ordinary skill, but instead teaches an alloy that includes no more than 500 ppm which would have included no less than the conventional minimum level of 50 ppm nitrogen; Smith ('542) does not disclose or in any way suggest an alloy including the very low levels of nitrogen, less than 30 ppm, that are critical to the fatigue performance of the alloy recited in claim 1; and the Examiner's conclusion that the Appellant did not show "unexpected results over the prior art range of 0 to 500 ppm" is fundamentally flawed given that Smith ('542) does not each a range of 0 to 500 ppm nitrogen; the Examiner has not provided any rationale providing sufficient support for his apparent position that the evidence submitted in the Present Application does not prove the existence of unexpected results.

In response, the Appellant has offered no evidence that alloy disclosed by Smith ('542) had a minimum of 50 ppm nitrogen. Just because the Appellant had possession of a conventional MP35N alloy does not necessarily mean that the Appellant had the same alloy made by Smith (‘542) since Smith (‘542) does not refer to the disclosed alloy as being an MP35N alloy. Evidence of unexpected properties may be in the form of a direct or indirect comparison of the claimed invention with the closest prior art which is commensurate in scope with the claims. MPEP 716.02(b)(III). Thus, the Appellant has not compared to the closest prior art. The Examiner further notes (see Table 9) that the standard MP35N alloy has an improved fatigue resistance over modified MP35N alloy at a stress value of 250 ksi. At 250 ksi standard MP35N alloy withstood 116% (11,129/9,586) the number of cycles in rotary beam fatigue testing than wire produced from modified MP35N alloy. Since the pending claims do not recite a stress value or range of stress values applied to the alloy for which the fatigue resistance of the modified MP35N alloy is greater than the fatigue resistance of the conventional MP35N alloy there are stress values (i.e. 250 ksi) where standard MP35N alloy has better properties than modified MP35N alloy, the modified MP35N alloy would not patentably distinguish from the conventional MP35N alloy. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Secondary Considerations: Commercial Success

Fifteenth, the Appellant primarily argues that the Myers Declaration shows that (1) a small diameter wire produced from the alloy recited in claim 1 has enjoyed very

substantial commercial success and (2) the commercial success is directly attributable to the unexpectedly and substantially improved fatigue resistance of the alloy. The Appellant also disagrees with the Examiner's position that the Myers Declaration is not commensurate in scope with the claims because the declaration is directed to a wire while the independent claim is directed merely to an alloy composition. The Appellant further argues that a sufficient nexus between the evidence of commercial success and the merits of the claimed invention was established and the Examiner has no reasonable basis for refusing to accept that the evidence confirms the non-obvious character of the claimed invention; the evidence from the Myers Declaration is not Mr. Myers's opinion, but rather direct evidence, as told to Mr. Myers by the customers themselves, that the customer'' orders for 35N LT wire were motivated by the product's superior fatigue properties and it is asked what could be more focused and compelling on the issue of why the customers purchased the product than a declaration from a knowledgeable person who had spoken with customers who purchased the product?

In response, the Examiner notes that the Appellant's opinion as to the purchaser's reason for buying the product is insufficient to demonstrate a nexus between the sales and the claimed invention since the Appellant has not shown whether or not the sales of 35N LT wire were based on heavy promotion or advertising, shift in advertising, consumption by purchasers normally tied to the Appellant or Assignee, or other business events extraneous to the merits of the Present Invention. Additionally, the commercial success of the 35N LT wire may have been attributable to extensive advertising and position as a market leader before the introduction of the instant product

(MPEP 716.03(b)(I)) and gross sales figures do not show commercial success absent evidence as to market share (MPEP 716.03(b)(IV)). Absent this information, the opinion of those providing the declaration is unpersuasive.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Jessee Roe/

Examiner, Art Unit 1793

Conferees:

/Roy King/

Supervisory Patent Examiner, Art Unit 1793

/Stanley Silverman/

Supervisory Patent Examiner, Art Unit 1793